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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/718,754 | 11/21/2003 | Stan V. Lyons | M881.12-0017 | 1446 |
| 164 | 7590 | 05/25/2004 | EXAMINER | |
| KINNEY & LANGE, P.A. THE KINNEY & LANGE BUILDING 312 SOUTH THIRD STREET MINNEAPOLIS, MN 55415-1002 | | | JOHNSTON, PHILLIP A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 2881 | |

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,754

Applicant(s)

LYONS ET AL.

Examiner

Phillip A Johnston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5-7-2004</u> . | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4,6-14, 16 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,8,9,11-19 and 21 of U.S. Patent No. 6,653,641. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to one of ordinary skill in the art that all the limitations in Claims 1-4,6-14, 16 and 17 of Application No. 10718754 are anticipated by Claims 1,2,8,9,11-19 and 21 of U.S. Patent No. 6,653,641. By way of example, a comparison of Claim 1 of Application No. 10718754, with Claim 1 of U.S. Patent No. 6,653,641 is included below.

Claim 1 of Application No. 10718754 reads as follows;

A bulk material irradiation system comprising:

an input for inserting bulk material;

a bulk material tube connected to the input and forming a path for bulk material flow;

a pumping assembly connected to the bulk material tube for forcing the bulk material to advance through the bulk material tube;

an irradiation assembly providing ionizing radiation that penetrates a full thickness of the bulk material to irradiate the bulk material passing adjacent to the irradiation assembly in the bulk material tube; and

an output for irradiated bulk material to exit the bulk material tube.

Claim 1 of U.S. Patent No. 6,653,641 reads as follows:

A bulk material irradiation system comprising:

an input for inserting bulk material;

a bulk material tube connected to the input and forming a path for bulk material flow;

a pressurizing assembly connected to the bulk material tube for forcing the bulk material to flow through the bulk material tube,

the pressurizing assembly comprising a pump assembly operable to remove oxygen from the bulk material flowing through the bulk material tube;

an irradiation assembly providing ionizing radiation that penetrates a full thickness of the bulk material to irradiate the bulk material passing adjacent to the irradiation assembly in the bulk material tube;

and an output for irradiated bulk material to exit the bulk material tube.

It is obvious to one of ordinary skill in the art that all the limitations in claims 1-4,6-14, 16 and 17 of Application No. 10718754 are anticipated by claims 1,2,8,9,11-19 and 21 of U.S. Patent No. 6,653,641.

Claims Rejection – 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,5-8 and 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2003/0129274 to Garwood, in view of Nablo, U.S. Patent No. 5,825,037.

Garwood (274) discloses a bulk material irradiation system that includes;

(a) An input for inserting ground meat; a bulk material tube connected to the input and forming a path for the ground meat to be transported (forced to flow through) between vessels with a pump; an irradiation assembly providing ionizing radiation to irradiate the bulk material passing adjacent to the irradiation assembly in the bulk material tube; and an output for irradiated bulk material to exit the bulk material tube, as recited in claims 1,16 and 17-19. See page 27, claim 18; and paragraphs [0136] and [0152];

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- (b) An electron beam directed directly at and through a stream of grinds while the grinds are passing through a tube, which is equivalent to penetrating the full thickness of the bulk material, as recited in claims 1, 16, and 17. See paragraph [0152];
- (c) Controlling the liquid contained in the ground beef, which is equivalent to the liquid bulk material, as recited in claims 15. See paragraph [0006] and [0119]; and
- (d) Ground meat velocity sensing and beam control, as recited in claim 19. See paragraph [0191].

Garwood (274) as applied above fails to teach the specific design limitations of the irradiation region of the bulk material tube, as recited in claims 5, 7, 8, and 12-14.

However, Nablo (037) discloses;

- (a) A semi-cylindrical treatment zone that has a Titanium window and a layer of high Z material attached to the cavity, as recited in claims 5, 7 and 8. see column 5, line 64-67; and Column 6, line 1-7;
- (b) Water cooled cavity walls, as recited in claims 12 and 14. See Column 8, line 19-21.

Therefore it would have been obvious to one of ordinary skill in the art that the ground meat irradiation apparatus and method of Garwood (274) can be modified to use the bulk material tube of Nablo (037), to provide a cross-sectional profile of the tube that provides maximum exposure to the electron beam, thereby the conditioned ground beef can be sterilized.

Garwood (274) and Nablo (037) disclose the claimed invention except for the use of a bulk material tube composed of titanium and a layer of stainless steel. However, it

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would have been obvious to one having ordinary skill in the art at the time the invention was made to use a bulk material tube composed of titanium and a layer of stainless steel, as recite in claims 7 and 8, since it have been held to be within the ordinary skill of worker in the art to select a known material on the basis of its suitability for the intended use. One would have been motivated to use a bulk material tube composed of titanium and a layer of stainless steel for the purpose of designing the irradiation treatment cavity capable of providing for both radiation and structural requirements, which Garwood (274) and Nablo (037) recognize.

Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945) The selection of a known material based on its suitability for its intended use supports a prima facie obviousness determination.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garwood (274) and Nablo (037) in view of McKeown (401).

The combination of Garwood (274) and Nablo (037) does not disclose irradiating the bulk material from two opposite sides, as recited in claim 2. However, McKeown (401) discloses an irradiation apparatus for delivering a charged particle beam on two sides of the material being irradiated. See Abstract.

Therefore it would have been obvious to one of ordinary skill in the art that the ground meat irradiation apparatus and method of Garwood (274) and Nablo (037) can be modified to use the dual beam path irradiation source of McKeown (401), to provide uniform irradiation of the ground meat which can thus be sterilized.

6. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garwood (274), Nablo (037) and McKeown (401) and in further view of Kanter (201).

The combination of Garwood (274), Nablo (037) and McKeown (401) does not disclose the use of a dosimetry carrier, as recited in claims 9-11. However, Kanter (201) discloses a dosimetry carrier for monitoring the irradiation of bulk material, as recited in claims 9-11. See Abstract.

Therefore it would have been obvious to one of ordinary skill in the art that the ground meat irradiation apparatus and method of Garwood (274), Nablo (037) and McKeown (401) can be modified to use the dosimetry carrier of Kanter (201), to monitor radiation incident within the bulk volume from a number of different directions in order to provide a more accurate indication of the average radiation dose.

Conclusion

7. 3. Any inquiry concerning this communication or earlier communications should be directed to Phillip Johnston whose telephone number is (571) 272-2475. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiners supervisor John Lee can be reached at (571) 272-2477. The fax phone number for the organization where the application or proceeding is assigned is 703 872 9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PJ

May 7, 2004



JOHN T. LEE
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